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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/640,822	08/17/2000	Heinrich Gers-Barlag	Bei 637- KGB	6834

7590 11/25/2003

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EXAMINER
WELLS, LAUREN Q

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 11/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/640,822	GERS-BARIAG ET AL.	
	Examiner	Art Unit	
	Lauren Q Wells	1617	

-- The MAILING DATE of this communication app ars on the cov r sh t with th correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 16-31 are pending. The Amendment filed 11/7/03, added claim 31.

The Terminal Disclaimer filed 11/7/03, is sufficient to overcome the double patenting rejection over US Patent No. 6,592,883.

Double Patenting Rejection Maintained

The rejection of claims 16, 19 and 23 under the judicially created doctrine of double patenting over claims 16, 19 and 23 of copending Application No. 09/641013 is MAINTAINED for the reasons set forth in the Office Action mailed 8/7/03, Paper No. 26.

Applicant has not argued against this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fanger et al. (6,153,204) in view of Msika et al. (5,939,054).

The instant invention is directed toward a cosmetic or dermatological stick preparation, which is a water-in-oil emulsion, comprising an oil phase which comprises 10-70% of fatty and/or wax components which melt above a temperature of 40 C, a water phase, at least one modified phyllosilicate pigment particles which exhibits both hydrophilic and lipophilic properties, at most 0.5% of one or more emulsifiers.

Fanger et al. teach cosmetic or pharmaceutical preparations with a reduced feeling of stickiness. The preparations are taught as emulsifier-free, water-in-oil lipodispersions. Lipsticks and deodorant sticks are taught as forms of the preparations, wherein the preparations are applied to the skin. Aluminum silicates, such as bentonites are taught as thickeners for use in the preparations. Paraffin oils, castor oil, isopropyl myristate, vaseline, lanolin, beeswax, ceresin, ozokerite, carnauba wax, candelilla wax and others are taught as preferred oily substances (fatty and/or wax components which melt above 40 C). UVA and UVB filters, iron oxides, zinc oxides, antioxidants, dyes, coloring pigments and bactericides are taught as additional additives for use in the preparations (additives/active ingredients, amphiphilic metal oxides). Water-in-oil emulsions are preferred forms of the composition. The reference lacks preferred modified hectorites and methods of preparing the emulsions. See Col. 2, lines 6-34; Col. 3, lines 9-61; Col. 6, lines 54-62; Col. 8, lines 1-19; Col. 9, line 16-Col. 10, line 29.

Msika et al. teach water-in-oil sunscreen emulsions in the form of sticks. Quaternium 14 and 18 hectorite are taught as gelling derivatives for use in the emulsions. These compounds are further taught as optimizing the stability of water-in-oil emulsions and potentiating the solar protection in the highest protection factors. Taught is a method of making the emulsion, wherein the aqueous phase is added to the fatty phase with slow stirring.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to exemplify the instant water-in-oil emulsions using the teachings of Fanger et al. because Fanger et al. teach emulsifier-free, water-in-oil emulsions comprising oily phase constituents that melt above 40 C and teach aluminum silicate (a phyllosilicate) as a thickener for use in the emulsion, wherein the emulsion can be in the form of a lipstick; hence, using the

teachings of Fanger et al. to arrive at the instant invention would be within the skill of one in the art.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to substitute the quaternium-18 hectorite of Msika et al. for the aluminum silicate in Fanger et al. because of the expectation of optimizing the stability of water-in-oil emulsions and of potentiating the solar protection of the emulsion, and because the replacement of one phyllosilicate gelling agent for the other, for cosmetic thickening purposes, would be within the skill of one in the art.

Regarding the term "lipodispersion" in Fanger et al., it is respectfully pointed out that water-in-oil emulsions are lipodispersions, as the definition of an emulsion, as given by Webster's Collegiate Dictionary, is a liquid dispersed with or without emulsifier in an immiscible liquid.

For the purposes of searching for an applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

Response to 35 USC 103 Arguments

Applicant argues, "the claims of Fanger et al. are directed toward a method of use wherein the composition/preparation used must contain a hydrophilic starch esterified with one

or more n-octenylsuccinate radicals. As such, the Fanger et al. reference is inapplicable to the scope of the applicants' claims where hydrophilic starch esterified with one or more n-octenylsuccinate radials are not present". This argument is not persuasive for two reasons, at least. First, the Examiner respectfully points out that it is well-established that consideration of a reference is not limited to the preferred embodiments or working examples, but extends to the entire disclosure for what it fairly teaches, when viewed in light of the admitted knowledge in the art, to person of ordinary skill in the art. In re Boe, 355 F.2d 961, 148 USPQ 507, 510 (CCPA 1966); In re Lamberti, 545 F.2d 747, 750, 192 USPQ 279, 280 (CCPA 1976); In re Fracalossi, 681 F.2d 792, 794, 215 USPQ 569, 570 (CCPA 1982); In re Kaslow, 707 F.2d 1366, 1374, 217 USPQ 1089, 1095 (Fed. Cir. 1983). The instant rejection is a 103-obviousness rejection and not a 102-anticipation rejection. Thus, the Examiner has relied upon the teachings of the reference as a whole and is not limited to consider merely the claims of the reference, as Applicant argues.

Second, the Examiner respectfully points out that Applicant's open-ended language, the transitional term "comprising", in the instant claims does not exclude any additional ingredients, such as a hydrophilic starch esterified with one or more n-octenylsuccinate radicals. Thus, Fanger et al. is applicable to the scope of Applicants' claims. Regarding the transitional phrase "consisting essentially of", as pointed out in the above rejection, for the purposes of searching for and applying prior art under 35 USC 102 and 103, absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to comprising. If an applicant contends that additional steps or material in the prior art are excluded by the recitation of "consisting essentially of", applicant has the burden of showing that the introduction of additional steps or

components would materially change the characteristics of applicant's invention. See MPEP 2111.03.

Applicant argues, "All of the other ingredients of Fanger et al.'s disclosure may be part of the preparation but there is no requirement for them to be present. As such, when taking each of the possible additional elements, the Fanger et al. reference teaches a virtual infinite number of possible permutations of the composition/preparation". This argument is not persuasive. The Examiner respectfully points out that Applicant appears to have misconstrued the preferred embodiments of Fanger et al. The Examiner first directs Applicant to Col. 2, lines 32-34, which states, "***W/O lipodispersions, which are the subject mater of the present invention***, are, by reverse analogy, ***emulsifier-free finely disperse*** preparations of the water-in-oil type". The Examiner second directs Applicant to Col. 10, line 35-Col. 12, line 30 and Col. 14, line 55-Col. 15, line 10, which exemplify such water-in-oil emulsions containing 10-70% of an oil phase, wherein the oil phase contains fatty and/or wax components which melt above a temperature of 40 C.

Applicant argues, "where is the factual support for the examiner's assertion that it would have been obvious to exemplify a particular embodiment of the invention when confronted with an infinite number of choices? There is none". This argument is not persuasive. The Examiner respectfully directs Applicant to the above rejection and the above paragraph for such factual support.

Applicant argues, "Fanger et al. recites a Markush-0like group of additional ingredients which may be present in the preparation. . .which includes emulsifiers. However, Fanger et al. is not only silent above the amount of emulsifier but also does not specifically teach the concept of

a specific range of emulsifier content (i.e 0-0.5% by weight". This argument is not persuasive. Again, the Examiner respectfully directs Applicant to Col. 2, lines 32-34, which states, "W/O lipodispersions, which are the subject mater of the present invention, are, by reverse analogy, ***emulsifier-free*** finely disperse preparations of the water-in-oil type". It is respectfully pointed out that the term "emulsifier-free" is synonymous to 0%.

Applicant argues, "when speaking to the issue of water-in-oil emulsions, Msika et al. discloses that the emulsifying system is between 4 and 35% by weight which is well in excess of the applicants' claimed range". This argument is not persuasive, as Msika et al. is merely relied upon to teach preferred modified phyllosilicates that are cosmetically acceptable for use in water-in-oil emulsions and for application to the skin of a user.

Applicant argues, "it is unclear how one of ordinary skill in the art would be able to pick and choose teachings for combination with Fanger et al. especially in light of the fact that the emulsion ranges are different between the two types of water-in-oil emulsions represented by Fanger et al. and Msika et al.". This argument is not persuasive. Again, the Examiner respectfully points out that Msika et al. is merely relied upon to teach preferred modified phyllosilicates that are cosmetically acceptable for use in water-in-oil emulsions and for application to the skin of a user. It is further respectfully pointed out that, as pointed out in the above rejection, Fanger et al. teach aluminum silicates as thickeners for use in their compositions, wherein aluminum silicates are phyllosilicates. Msika et al. teach quaternium 14 and 18 hectorites as thickeners for use in water-in-oil emulsions, wherein these compounds optimize the stability of water-in-oil emulsions and potentiate the solar protection in the highest protection factors. Thus, one of skill in the art would be motivated to add quaternium 18

hectorite to the water-in-oil emulsion of Fanger et al. or substitute quaternium 18 hectorite for aluminum silicate, as taught by Fanger, because of the benefits of quaternium 18 hectorite taught by Msika et al.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30), with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on (703)305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

11/24/03